

## R E M A R K S

Claims 1 and 3-11 are now in this application, and are presented for the Examiner's consideration.

### Prior Art Rejections

Claims 1, 3, 5-8 and 11 were rejected under 35 U.S.C. §103(a) as being obvious from newly cited U.S. Patent No. 4,896,768 to Anderson in view of U.S. Patent No. 6,547,468 to Gruenbacher et al.

However, it is respectfully submitted that one skilled in these art would NOT combine these two inventions to arrive at the present claimed invention, since there is NEITHER a suggestion NOR a logical reason to combine these references.

In the first place, the combination of Smith et (USP 5,562,642) and Gruenbacher et al was made in the last Office Action, and Anderson is essentially the same as Smith et al, but even further removed for the reasons given below, so that the same remarks made previously in regard to Smith et al also apply to Anderson.

Anderson discloses a planar pad packaged by plastic film for discardable wiping use. The pad 14, for example, a nonwoven fabric, is attached to one of the plastic sheets of packaging material. The pad is "presaturated" with diluted glutaraldehyde aqueous solution. In this patent, only a pad impregnated with

glutaraldehyde is disclosed. No other chemical substance is disclosed.

Two plastic sheets 12, 16 are bonded together so as to be peelable when used. They are bonded along the outermost peripheral line of the pad, as shown in Fig. 1. Sheets 12, 16 are tightly bonded such that the aqueous solution does not leak out.

There is NO disclosure or even a remote suggestion in Anderson concerning a capsule anywhere. Glutaraldehyde is highly germicidal and chemically stable by nature. Thus, there is NO logical reason or need to retain this substance in a capsule, even in the form of a diluted solution.

Furthermore, this wiping pad is used only for disinfectant use to clean the surface of apparatus, instruments, furniture or equipment, but is NOT used, or intended to be used, for human skin. For this use, the simpler the structure, the more convenient. There is thus NO need to provide a capsule in the package. In other words, the simplest structure without a capsule is the best way for this use according to Anderson.

Therefore, there is neither a disclosure nor a suggestion, and not even an implication, with regard to ANY capsule in this art. One skilled in this technological field would therefore NEVER take a capsule into consideration.

However, in an attempt to advance prosecution, claims 1 and 11 have been amended to recite that the breakable leakproof blister containing one dose of the substance is for application to skin of a person. Support for the same is found at page 1, lines 2-7 (paragraph [0001]) of the present application. Since no structural limitations have been added to the claim, it is submitted that there are no new issues that are presented herein.

In the patent to Smith applied in the previous Office Action, it was noted that Smith specifically states that a package equipped with a breakable reservoir therein having a weak point is improper to use due to unexpected rupture or leakage in transportation (column 3, lines 11-22 and 45-50). Certainly, the same statement would apply to Anderson since a similar structure is provided. As such, there is still a clear teaching away of this structure in the prior art. As such, Smith et al designed the system thereof to avoid these problems in a system of the type disclosed by Gruenbacher et al. See column 3, lines 51-63 of Smith et al. The same remarks would therefore apply to Anderson in which the structure is similar.

There is thus evidence in the prior art against combining Anderson with the rupturable blister of Gruenbacher et al. Thus, one skilled in the art, would seek to avoid the structure of Gruenbacher et al.

As discussed in the previous Office Action, Gruenbacher et al discloses an applicator equipped with a dosing reservoir. This reservoir comprises two chambers to control liquid flow inside an applicator. As stated above, there is not even a remote suggestion regarding use of a protective cover, as claimed in the present application, in Gruenbacher et al.

It is further noted that, with the structure of Gruenbacher et al, it is difficult to pour the liquid uniformly to the surface of the applicator. The liquid inside the reservoir will flow out only within a localized area, which provides a disadvantage that is overcome with the structure of the present claimed invention.

It is therefore submitted that, not only is there no suggestion or logical reason to combine the references, and not only does Anderson and related prior art teach away from such a combination, but also, it would be difficult for a person skilled person in the art to combine these inventions.

Thus, although Gruenbacher et al discloses an applicator having a reservoir therein, the reservoir contains a composition for application. However, there is NO disclosure, statement or even a remote suggestion regarding a protecting cover. The technological feature of Gruenbacher et al is characterized in that the flow of composition (usually in liquid form) is controlled so as to flow towards a designed direction when

pressure is applied onto the reservoir. This is to prevent contamination from a user's hands when using the same.

The essence of Gruenbacher et al lies in the applicator structure WITHOUT a protecting cover. In reverse, if Gruenbacher et al were the applicator with a protecting cover, there would be NO need to control the flow of composition at all.

Therefore, there is no disclosure, implication or suggestion anywhere in Gruenbacher et al with regard to providing a protecting cover. It is submitted that a person skilled in in this technological field would therefore NEVER take the protecting cover into consideration in Gruenbacher et al.

As stated in the Amendment filed in response to the last Office Action, it is not the mere possibility of combining the references that must be taken into consideration, but rather there must exist some logical reason or some suggestion in the art for combining the references. W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983); ACS Hospital Systems, Inc. v. Montefiore Hospital et al.; 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984); In re Imperato, 179 U.S.P.Q. 730, 732 (C.C.P.A. 1973).

It is submitted that there is no suggestion or logical reason to modify Anderson in view of Gruenbacher et al, absent the teachings of the present claimed invention. Anderson is directed to a flat sheet-like structure, and would not accommodate a blister therein. Further, there is no pouch in

Anderson that encompasses sheets and which pouch is secured to an inside face of one of the separable parts 12, 16.

Gruenbacher et al, on the other hand, does not provide any protective cover, but rather, the sheet surrounding the blister in Gruenbacher et al is the applicator itself. Thus, the outer sheet 15 is a permeable membrane (column 3, line 38). The same holds true as to outer sheet 64 in the embodiment of Fig. 6 (column 8, lines 1-20). There is no disclosure or even a remote suggestion of a protective cover in Gruenbacher et al, let alone one having an inner surface to which a pouch having a blister therein is secured, as claimed herein.

In fact, not only is there no logical reason or suggestion in the art for combining the references, but as discussed above, the prior art via Smith et al, which is similar to Anderson, actually teaches away from such a combination. Further, Anderson is not directed to holding a topical ingredient for application to a person's skin, but rather, is directed to holding a disinfectant for appliances, etc. and therefore, the same considerations of construction would not come into play.

In this regard, claim 1 recites three important and distinct elements, namely:

a protective cover made of two separable parts of leakproof material,

a breakable leakproof blister containing one dose of a substance, and

a pouch comprising an applicator, with the blister housed in the pouch and the pouch fixed to an inside face of one of the two separable parts.

This combination is nowhere disclosed or even remotely suggested by the references, taken individually or in combination.

As to claims 6 and 11, it is submitted that the Examiner has misunderstood the limitation "significantly greater than" in these claims. Specifically, it was stated that "Anderson teaches closed outline junction line 18/20/22/24 surrounding the applicator in an area significantly greater than the applicator area 20." However, it is submitted that the term "significantly greater than" in these claims means that the junction line is formed well away from the pouch as shown in Figs. 2 and 4 of the present application. For example, a measurement in Fig. 2 shows the entire width of pouch 24 being 2.8 cm, while the width or distance between opposite side edges of junction line 35 is 4.0 cm.

Anderson, on the other hand, merely discloses that "first layer 12 is heat sealed to second layer 16 along each of edges 18, 20, 22 and 24" (column 3, lines 61-62, Fig. 1). The sealed line is formed immediately adjacent to the pad surrounding it. Moreover, Anderson states "Proportionately larger amounts of

liquid are used for larger sized pads" (column 3, lines 59-60). Based on this statement, it is submitted that one skilled in the art in this technological field would design the size of the pad to the maximum extent within the package.

Therefore, according to this meaning, the arrangement of the pad (pouch) to the sealed line is entirely different between Anderson and the present claimed invention.

The present claimed invention enables users to handle and apply any kind of composition more easily during application in use, as described at page 5, lines 13-27 (paragraph [0022]) and page 6, lines 11-18 (paragraph [0025]). Further, the present claimed invention aims at application onto the skin, as described at page 1, lines 2-7 (paragraph [0001]), such that when the pouch is separated away from the sealed line, users can apply any composition onto their skin, even onto wound areas, as described at page 1, lines 26-29 (paragraph [0003]), without irritation.

According to the structure of the present claimed invention, one can even apply the composition to a restricted region selectively, for example, even a narrow region on the skin without affecting other regions.

Furthermore, the present claimed invention enables a manufacturer to handle even an unstable composition, because such composition can be stored in the closed capsule.



Accordingly, it is respectfully submitted that the rejection of claims 1, 3, 5-8 and 11 under 35 U.S.C. §102(b) has been overcome.

Claim 4 was rejected under 35 U.S.C. §103(a) as being obvious from Anderson and Gruenbacher et al as applied above, and further in view of U.S. Patent No. 4,762,124 to Kerch et al.

The remarks previously made above in regard to Anderson and Gruenbacher et al are incorporated herein, and therefore not repeated.

Kerch et al was merely cited for teaching the use of cotton wool 20 inside an applicator 10 with a permeable membrane 22. However, Kerch et al fails to cure any of the aforementioned deficiencies of Anderson and Gruenbacher et al.

Accordingly, it is respectfully submitted that the rejection of claim 4 under 35 U.S.C. §102(b) has been overcome.

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being obvious from Anderson and Gruenbacher et al as applied above, and further in view of U.S. Patent No. 6,695,515 to Fleury and U.S. Patent No. 5,511,689 to Frank.

The remarks previously made above in regard to Anderson and Gruenbacher et al are incorporated herein, and therefore not repeated.

Fleury fails to disclose or even remotely suggest the limitations of a pouch fixed to the inside face of one of two separable parts, with the pouch comprising an applicator, and the blister being housed in the pouch, such that the applicator is impregnated with the substance when the blister is broken. Rather, at most, Fleury discloses two separable parts with a blister therein, without any further structure of the claimed pouch.

Frank was merely cited for teaching an adhesive dressing 1 and cover 4 applicable to the external surface of a film 6 with the outside surface of dressing 1 weakly secured to an inside face cover 4. However, Frank al fails to cure any of the aforementioned deficiencies of Anderson, Gruenbacher et al or Fleury.

Accordingly, it is respectfully submitted that the rejection of claims 9 and 10 under 35 U.S.C. §102(b) has been overcome.

#### Double Patenting

Claims 1-11 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending application no. 10/539,266 in view of the Gruenbacher et al patent.

In this regard, enclosed is a Terminal Disclaimer, which terminally disclaims the portion of any patent granted on the present application, to expire at the same time as any patent granted on application no. 10/539,266. The appropriate Terminal Disclaimer fee is being paid with this Amendment.

Accordingly, it is respectfully submitted that the rejection of claims 1-11 on the ground of non-statutory obviousness-type double patenting, has been overcome.

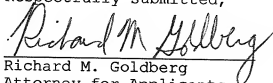
If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper, to Account No. 07-1524.

The Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1524.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1 and 3-11 are allowable, and early and favorable consideration thereof is solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Richard M. Goldberg". The signature is written in dark ink and is positioned above a horizontal line.

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